

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re App : Robert A. Ersek et al

S.N. : 07/863,848

Filed : April 6, 1992

July 6, 1992

Art Unit 3308

Our Docket No.
910759.ORI

For : TREATMENT OF UROLOGICAL AND
GASTRIC FLUID REFLUX DISORDERS
BY INJECTION OF MICRO PARTICLES

INFORMATION DISCLOSURE STATEMENT

The Commissioner of Patents and Trademarks

Washington, D.C. 20231

Sir:

In recognition of the obligations imposed upon applicants and their attorneys and assigns under 37 CFR 1.56, the accompanying list identifies prior art related to the invention described in the above-captioned application.

The references listed on the attached form are cited for consideration by the Patent and Trademark Office, but no representation is hereby made that the references are "prior art" within the meaning of 35 U.S.C. §§ 102 or 103. Moreover, the explanation following below is not to be taken as a representation that the references have been thoroughly reviewed. In particular,

no representation as to the relative relevance of any portion of a reference is intended.

PTO Form 1449 was not used because of the rather large number of references involved. Many of the references were brought to the applicants' attention pursuant to litigation concerning similar subject matter, and applicants believe that they have sufficient relevance to be considered. If this is not satisfactory, applicants are prepared to do the necessary listing.

EXPLANATION OF DOCUMENTS

Whereas the documents (with three exceptions) are in the English language, because of the rather extensive nature of the citations, the following discussion is submitted as a guide to help the Examiner sort through them.

U.S. Patent 4 093 576, issued to deWijn, discloses PMMA beads suspended in a water soluble gel. PVP is identified also as a suitable gel material.

U.S. Patent 4 186 189, issued to Shalaby et al, includes drug-bearing polymers ground into 1-200 micron sized particles. The particles are then suspended in an aqueous solution to which other materials, such as carboxymethyl cellulose, PVP, surface acting agents and dextrose, may be added.

U.S. Patent 4 565 580, issued to Teruo Miyata et al, discloses an aqueous solution of collagen beads which can be used for cell culture or for measuring adhesion activity of blood platelet.

U.S. Patent 4 582,640, issued to Thomas L. Smestad et al, discloses a soft tissue implant material of collagen dispersed in an isotonic aqueous medium. The material is injectable.

U.S. Patent 4 592 864, issued to Teruo Miyata et al, discloses an aqueous atelocollagen solution which remains fluid until injected into living bodies.

U.S. Patent 4 631 188, issued to Vladimir A. Stoy et al, discloses a solidifying physiologically acceptable polymeric composition for injectable implantation.

In U.S. Patent 4 652 441, issued to Hiroshi Okada et al, columns 8-9 disclose use of the microcapsules in an injectable preparation.

U.S. Patent 4 803 075, issued to Wallace et al, describes the use of injectable aqueous solutions containing collagen and a fluid lubricant.

U.S. Patent 4 882 607, issued to Leslie L. Balassa, discloses an injectable cartilage extract.

U.S. Patent 4 828 827, issued to Alex M. Henderson et al, discloses an injectable PVP aqueous gel for soft tissue augmentation.

U.S. Patent 4 837 285 issued to Richard A. Berg et al, discloses injectable collagen beads for soft tissue argumentation.

U.S. Patent 5 007 940, issued to Eric P. Berg, discloses injectable polymeric bodies for soft tissue augmentation.

U.S. Patent 4 894 231, issued to Jacques-Pierre Moreau et al, discloses injection of biodegradable polymers for a drug delivery system.

U.S. Patent 4 061 731, issued to Sheldon K. Gottlieb, discloses injecting finely divided collagen in a saline water for soft tissue augmentation.

U.S. Patent 4 197 846, issued to Louis Bucalo, discloses an injectable soft tissue implant.

U.S. Patent 4 212 857, issued to Leslie L. Balassa et al, discloses injectable aqueous cartilage extract.

U.S. Patent 4 341 691, issued to David A. Anuta, discloses an injectable bone cement.

U.S. Patent 4 424 208, issued to Donald G. Wallace et al, discloses injectable collagen in an aqueous carrier for soft tissue augmentation.

U.S. Patent 4 469 676, issued to Michael Hecmati, discloses an injectable soft tissue augmentation composition of cartilage particles dispersed in a liquid.

U.S. Patent 5 011 494, issued to von Recum et al, discloses a soft tissue implant with micron scale surface texturing designed to be partially embedded but not encapsulated upon implant.

Arnold, Godfrey E., "Vocal Rehabilitation of Paralytic Dysphonia", Archives of Otolaryngology, 62:1-17 (1965) describes ground cartilage suspended in water, possibly sesame oil, used for injection. See, for example, page 4.

Balazs, E. A. et al, "The Replacement of the Vitreous Body in the Monkey by Reconstituted Vitreous and by Hyaluronic Acid", "Surgery of Retinal Vascular Diseases", Colloque, Amerstoort 1963. Mod. Probl. Ophthal., 4:230-232 (Karger, Basel/New York 1966). Balazs discloses collagen suspended in saline solution to which hyaluronic acid may be added.

Mentor O&O Inc. "Mentor Polytef Paste" package labeling. Mentor Polytef Paste package labeling includes relatively smooth polytetrafluoroethylene (Teflon) beads suspended in glycerine and a minor amount of polysorbate. This paste is used for injection for soft tissue augmentation. This particular product has had problems reported with respect to particle migration from the injection site due to the size and smooth nature of the particles.

The additional references on the attachment are of interest because they pertain to the use of injectable collagen, Teflon®, cartilage or other compatible tissue augmentation material.

The references listed next below are cited ad explained in the specification:

- (1) Bradley and Timm, "Treatment of urinary incontinence by implantable prosthetic sphincter", Urology, 1:252 (1973);
- (2) Kaufman, "Treatment of post-prostatectomy urinary incontinence using a silicone gel prosthesis", Brit. J. Urol., 48:646 (1973);

- (3) Kaufman, "Treatment of post-prostatectomy urinary incontinence using a gel prosthesis", Brit. J. Urol., 45:646 (1973);
- (4) Malizia et al, JAMA, Volume 251, No. 24, pp. 3277-3281 (1984);
- (5) U.S. Patent No. 4 773 393;
- (6) U.S. Patent No. 4 803 075;
- (7) U.S. Patent No. 3 638 649;
- (8) U.S. Patent No. 3 657 744;
- (9) U.S. Patent No. 4 239 492;
- (10) U.S. Patent No. 4, 240 794;
- (11) Rhodes, J. E., "Various plasma expanders in man", ANNUAL, NEW YORK ACADEMY OF SCIENCE, 55:522-525, 1952;
- (12) Harwicke, J., Advances in Nephrology, 2:61074, 1972;
- (13) Kojima, M., Takahashi, K. & Honda, K., "Morphological study on the effect of polyvinylpyrrolidone infusion upon the reticuloendothelial system, TOKYO J. EXP. MED., 92:27-54, 1967);
- (14) O'Donnell and Puri, "Technical refinements in endoscopic correction of vesicoureteral reflux", The Journal of Urology, Vol. 140, November, 1988, pp 1101-1102;
- (15) Politano, "Periurethral polytetrafluoroethylene injection for urinary incontinence", The Journal of Urology, Vol. 127, March, 1982, pp. 439-442.

Copies of all but three of these references are enclosed for your review. We have been unable, thus far, to locate a copy of each of the following three references:

- (1) Bradley and Timm, "Treatment of urinary incontinence by implantable prosthetic sphincter", Urology, 1:252 (1973);
- (2) Kaufman, "Treatment of post-prostatectomy urinary incontinence using a silicone gel prosthesis", Brit. J. Urol., 48:646 (1973); and
- (3) Kojima, Takahashi and Honda, "Morphological study of the effect of polyvinylpyrrolidone infusion upon the reticuloendothelial system", TOKYO J. EXP. MED., 92:27-54, 1967.

The following references are in either the French or German language. Applicants do not have translations other than the summaries as enclosed.

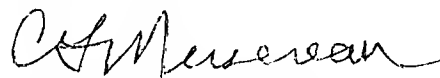
- (1) Matouschek, E., "Treatment of Vesicorenal Reflux by Transurethral Teflon-Injection", Urologe A (1981) 20:263-264;
- (2) Landes, E., "Application Modalities and Experiences with Collagen in the Treatment of Folds and Scars", Z. Hautkr. 60, Heft 16 (1985); and
- (3) Schnitzler, L., R. Baran, Arrouy, M. Dubertret, L. and Halan, M., "Reponses Cutanees a L'Implant de Collagene Injectable (Zyderm)", Ann. Dermatol. Venereol., 1984, 111, No. 2.

It should be noted that it is the combination of the size and the irregular surface nature of the particles of the present invention which cooperates to prevent migration of the particles from the injection site. Thus, larger particles having smoother surfaces, such as polytetrafluoroethylene micro spheres, may fall within the size range but also may be of a character or nature which allows them to migrate to different bodily sites from that of the injection, whereas much smaller polytetrafluoroethylene particles of irregular shape would not migrate. After injection, the gel phase of the material (not the particles) is replaced by a fibrin and protocollagen matrix surrounding each of the micro particles. In this manner, the soft tissue augmentation becomes permanent with the encapsulation of the particles in the matrix of host collagen fibrils.

Consideration of the references is requested.

Respectfully submitted,

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Enclosures